Q26. How useful do you consider the following measures to facilitate sharing and use of data sets for the development and testing of Artificial Intelligence in healthcare?

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not at all</th>
<th>To a limited extent</th>
<th>To some extent</th>
<th>To a great extent</th>
<th>Completely</th>
<th>I don’t know / No opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to health data by Artificial Intelligence manufacturers for the development and testing of Artificial Intelligence systems could be securely, including compliance with GDPR rules, facilitated by bodies established within the EHDS</td>
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<td>Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data, annotation/labelling) to data holders to promote suitability of their health data for Artificial Intelligence development.</td>
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<tr>
<td>Bodies established within the EHDS, alone or with other bodies established under the Testing and Experimenting Facilities, provide technical support to medicine agencies, notified bodies for medical devices, and other competent bodies in their supervision of Artificial Intelligence products and services</td>
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<tr>
<td>Other</td>
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</tbody>
</table>

**Please specify:**

We agreed with these points.
Q27. In your view, is the introduction of Artificial Intelligence in healthcare creating a new relationship between the Artificial Intelligence system, the healthcare professional and the patient?

○ Yes
○ No
○ I don't know/No opinion

Please specify:

Yes:
AI algorithms have the potential to improve diagnosis and personalize treatment. The former requires access to population level data, and personal medical history and genetic data. The latter requires access to personal medical history and genetic data. The introduction of AI algorithms inevitably disrupts the relationship between the healthcare professional and the patient.

In the short-term it is likely that AI algorithms will be used as a diagnostic tool by healthcare professionals, almost like a standard test. The final judgement and responsibility will still lie with the healthcare professional, though this may have little impact on the relationship between the healthcare professional and the patient.

In the medium-term, the trust which traditionally existed between the patient and the healthcare professional will partially be placed in the AI algorithm. A new trust relationship thus must be established between the healthcare professional and the AI algorithm. Establishing the trustworthiness of AI algorithms is a significant challenge and, until the output of such systems become more explainable, this challenge will remain. Perceptions of algorithmic security during training and operation -- both in terms of the system’s ability to protect data and its resilience when attacked – also will inform whether and when this trust relationship can successfully be constructed.

Other important questions include: 1) As AI algorithms become more embedded in routine healthcare environments, how will patients react when, inevitably, their healthcare professional does not follow the recommendation of the AI system; 2) Will patients have access to both the AI system’s recommendation and the healthcare professional’s decision; 3) How will that affect patient trust in healthcare professionals (and in the AI); 4) Will healthcare professionals be assessed based on their “performance” potentially redefined as how well they follow the recommendations of the AI; and 5) Will this dynamic produce a culture in which healthcare professionals could be is tempted to follow an AI system’s recommendations to be “safer”?

In the longer term, the deployment of AI algorithms could lead to the de-skilling of healthcare professionals. As they come to trust AI systems more and more (or simply opt to routinely follow their recommendations), they could become more likely to lose their expertise and potentially their ability to detect wrong AI recommendations (see also our response to Q29). The problem here is that most AI systems assign users a passive role by making recommendations rather than creating a cooperative decision-making process in which human users can apply their expertise. This is an inherent fallacy in the “human-in-the-loop” approach that transcends issues of trustworthiness and transparency in AI systems. Permitting a human “the last word” in such systems is not sufficient to address this issue. What is needed are real human/AI partnerships.
Supplementary point in answer to Q28 (in final comments box in questionnaire due to formatting):

Stating that AI developers must train healthcare professionals and that healthcare professionals must demonstrate understanding of the limitations of AI implies that health professionals must adapt to AI systems. This framing ignores the essential converse approach: how can and should healthcare professionals influence the design of AI systems, not merely by providing input and data to be processed by AI algorithms, but by compelling AI systems to fully take into account professionals’ work practices and all anticipatable effects of putting “the computer in the loop.”
The most significant ethical issue is the capability of the AI system to do harm to the patient if appropriate safeguards are not in place. While earlier questions have highlighted the role of a physician in diagnosis and treatment, we have seen elsewhere that over-reliance on poorly understood technologies can impede independent decision making (e.g., reliance on electronic calculators leading to a deterioration in basic arithmetic skills). The ethical issue when such circumstances arise is who bears responsibility: 1) if the system was wrong but the professional did not spot it, or 2) if the system was right but overruled by the professional?

If only the human bears responsibility, as opposed to sharing it with the designer/provider of an AI system, decision-making by health professionals could be undesirably influenced and put pose ethical dilemmas for health practitioners (e.g. “Should I take the risk of overruling the AI system, or should I confirm its recommendation even though I have a doubt because I can’t afford the risk of being wrong?”)

These additional ethical issues also bear emphasis:

1) some AI systems in healthcare applications are based on tracking and collecting long-term measurements from patients using mobile applications or wearables. Although the GDPR might apply, it is not clear to what extent it or other such statutes can prevent the sharing or sale of patient data to 3rd parties, such as insurance companies. On the other hand, healthcare data can be helpful for scientific research/open innovation. That said, currently, tracking information by smartphone apps (e.g., location data) is mostly gathered for commercial use instead of scientific research or innovation; and

2) Algorithms and data used for training them must be free from any kind of identifiable and preventable bias. We may consider this problem more generally as a principle of equal access to the benefits of AI for healthcare, regardless of gender, ethnicity, or any other characteristic.
Q30. Are there general comments you would like to make about measures needed to support the appropriate and trustable development, deployment and use of Artificial Intelligence in healthcare that would be aiding the best interest of the patients?

Thank you for your contribution to this questionnaire. In case you want to share further ideas on these topics, you can upload a document below.

Please upload your file:
Only files of the type .pdf,.txt,.doc,.docx,.odt,.rtf are allowed

Final comments: